

Amendments to the Claims:

This listing of claims will replace all prior versions, and listing, of claims in the application:

Claim 1 (Currently Amended): A method for the treatment of Type 2 diabetes mellitus and conditions associated with diabetes mellitus, which method comprises the administration to a human or non-human mammal in need thereof, of an effective non-toxic amount of an insulin sensitiser, wherein the insulin sensitiser is 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof, in a pharmaceutically acceptable form, so as to provide a plasma concentration of the insulin sensitiser of at least a threshold level (the 'Threshold Plasma Concentration') from within the range of effective plasma levels of the insulin sensitiser.

Claim 2 (Original): A method according to claim 1, wherein the Threshold Plasma Concentration is within the range of from about 40 to about 200ng/nL.

Claim 3 (Currently amended): A method according to ~~claim 1~~ or claim 2, wherein the Threshold Plasma Concentration is within the range of from about 50 to about 120ng/mL or about 60 to about 120ng/mL or about 90 to about 110ng/mL or about 95 to about 105ng/mL.

Claim 4 (Currently amended): A method according to ~~any one of claims 1 to 3~~ claim 1, wherein a minimum value of the Threshold Plasma Concentration (or the Minimum Threshold Plasma Concentration) of the insulin sensitiser is its SC50 concentration.

Claim 5 (Currently amended): A method according to ~~any one of claim 1 to 4~~ claim 4, wherein a Preferred Threshold Plasma Concentration for the insulin sensitiser is twice the SC50 concentration.

Claim 6 (Currently amended): A method according to ~~any one of claim 1 to 5~~ claim 5, wherein the plasma concentration of the insulin sensitiser remains substantially within the range from the Minimum Threshold Plasma Concentration to a level at or above the Preferred Threshold Plasma Concentration.

Claim 7 (Cancelled).

Claim 8 (Currently amended) A method according to ~~any one of claims 4 to 6~~ claim 4, wherein ~~the insulin sensitiser is Compound (I) and~~ the SC50 of the insulin sensitiser is within the range of 40 to 65 ng/mL.

Claim 9 (Currently Amended): A method according to claim 8, wherein the SC50 ~~of Compound (I)~~ is 51.4ng/mL.

Claim 10 (Currently amended): A method according to ~~any one of claims 6 to 9~~ claim 5 wherein ~~the insulin sensitiser is Compound (I) and~~ the Preferred Threshold Plasma Concentration is in the range of about 80 to about 130 ng/mL or about 82.2 to about 123.4ng/mL.

Claim 11 (Currently Amended): A method according to claim 10, wherein the Preferred Threshold Plasma Concentration ~~for Compound (I)~~ is 100 ng/mL or 102.8 ng/mL.

Claim 12 (Currently Amended): A method according to claim 1, wherein the ~~insulin sensitiser is Compound (I) and~~ its plasma concentration of the insulin sensitiser remains substantially within the range of from 40 ng/mL to at or above 130 ng/mL or 41.1 ng/mL to at or above 123.4 ng/mL, for example 50 ng/mL to at or above 100 ng/mL or 51.4 ng/mL to at or above 102.8 ng/mL.

Claim 13 (Currently Amended): A method according to claim 10, wherein the ~~insulin sensitiser is Compound (I) and~~ its plasma concentration of the insulin sensitiser remains substantially at or above its Preferred Threshold Plasma Concentration.

Claim 14 (Currently Amended): A method according to claim 13, wherein the ~~insulin sensitiser is Compound (I) and~~ its plasma concentration of the insulin sensitiser remains at or above 100 ng/mL or substantially at or above 102.8 ng/mL.

Claim 15 (Cancelled).

Claim 16 (Currently Amended): A pharmaceutical composition comprising an insulin sensitiser, wherein the insulin sensitiser is 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof, in a pharmaceutically acceptable form, and a pharmaceutically acceptable carrier therefor, which composition is adapted to provide a plasma concentration of the insulin sensitiser of at least a Threshold Plasma Concentration of the insulin sensitiser.

Claim 17 (Currently amended): A pharmaceutical composition according to claim ~~17~~ 16 wherein the composition is adapted to provide a plasma concentration of the insulin sensitiser of at least a Threshold Plasma Concentration over a sustained period of time.

Claim 18 (Currently Amended): A modified release pharmaceutical composition comprising an insulin sensitiser, wherein the insulin sensitiser is 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, or a tautomer thereof, in a pharmaceutically acceptable form, and a pharmaceutically acceptable carrier therefor, which composition is adapted to provide a plasma concentration of the insulin sensitiser of at least a Threshold Plasma Concentration of the insulin sensitiser.

Claim 19 (Currently amended): A modified release composition according to claim ~~1~~ 18 being a delayed, pulsed or sustained release composition.

Claim 20 (Currently amended): A composition according to ~~any one of claim 16 to 19,~~ adapted to provide a method of treatment according to ~~any one of claims 1 to 15~~ claim 1.

Claim 21 (Original): A method by which the Threshold Plasma Concentration for a given anti-diabetic compound can be determined by the steps:

- 1) first to obtain plasma concentrations versus time data for the compound by using standard pharmacokinetic compartmental modelling methods;
- 2) the model predicted concentrations for the compound are then fed back into the model and used to determine the change in fasting plasma glucose levels after various doses;
- 3) the relationship between predicted plasma concentrations of compound and fasting plasma glucose can then be determined using an indirect pharmacological response model.